

REMARKS

Claims 14, 17-19, 21-24, 27, 28, 31, 34-37 and 39-41 remain pending in the present application. Amendments presented herewith are merely formal in nature, and do not present new matter.

Rejection for Double Patenting

Claims 14, 17-19, 21-24, 27, 28, 34-37 and 39-41 stand rejected under the judicial doctrine of nonstatutory obviousness-type double patenting over U.S. Serial No. 12/021,546. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

According to the Examiner's notice of a non-responsive reply, issued on March 15, 2010, the Examiner states:

A complete response to a rejection entails either arguments directed to the merits of the rejection or the filing of a terminal disclaimer.

Applicants submit that the response of December 16, 2009, reproduced below, is fully responsive since Applicants did indeed present arguments "directed to the merits of the rejection", i.e. that the provisional double patenting rejection is improper on procedural grounds, in light of the allowability of the claims as amended and in view of Applicants' arguments against the prior art rejection. To require Applicants to submit a terminal disclaimer in an earlier-filed application over a later-filed application, especially prior to an indication of allowable subject matter is improper.

Accordingly, Applicants reiterate their comments in traverse of the provisional double patenting rejection, below. In the alternative, Applicants

request the Examiner to hold the rejection and the requirement for a terminal disclaimer in abeyance until a notice of allowable subject matter is indicated in the present application, at which time Applicants will consider the propriety of filing a terminal disclaimer. As such, a prompt action on the merits of the case is requested.

As a further alternative, if the Examiner is still disposed to object to the responsiveness of the present reply, Applicants request that this reply be considered as a petition under 37 C.F.R. 1.181 to the Director for review of the Examiner's determination of a non-responsive reply.

Applicants direct the Examiner's attention to MPEP 804 I.B.1, wherein procedures for dealing with non-statutory double patenting rejections are set forth:

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. MPEP 804 I.B.1 (Emphasis added).

Since the claims are patentable over the cited reference, as will be discussed below, the only remaining rejection is a non-statutory double patenting rejection, and as such the Examiner should withdraw the rejection and permit the present application to issue, without a terminal disclaimer.

Rejection under 35 U.S.C. §103(a) over Pacetti et al.

Claims 14, 19, 28 and 38 stand rejected under 35 U.S.C. §103(a) over Pacetti et al. (U.S. Patent No. 7,056,591). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

Pacetti et al. disclose a medical article, comprising an implantable substrate having a coating deposited on the substrate, the coating comprising a polymer, the polymer being a product of co-polycondensation of a diketene acetal and a diol, which is a polyorthoester (col. 2, lines 14-17).

The Pacetti et al. coatings are invariably disclosed for use on medical devices, such as stents, so as to form a drug "reservoir layer", wherein a drug is stored in the polyorthoester coating (col. 3, lines 25-32) for continuous delivery upon implantation of the stent into a diseased site (col. 1, lines 46-48).

Pacetti et al. fail to disclose a composition or delivery vehicle suitable for local, non-systemic administration of a drug to a body and directly to tissue within a body cavity, as claimed herein. Pacetti et al. also fail to disclose or suggest a delivery vehicle selected from the group consisting of microcapsules, microspheres, barriers, liposomes, osmotic pumps, fibers, filaments, gels, foams and films, as presently claimed. Further, Pacetti et al. fail to disclose or suggest that their vehicles should contain Pemirolast or an analog thereof in an amount effective to inhibit formation of post-operative adhesions, as claimed herein.

Upon consideration of the Pacetti et al. disclosure as a whole, one skilled in the art would not have been motivated to coat the Pacetti et al. composition directly onto injured body tissue, since Pacetti et al. invariably disclose coating their compositions onto a medical device for subsequent implantation to a diseased site in the body.

"[T]he test is whether the combined teachings of the prior art, taken as a whole" suggest the modifications to the skilled artisan. *In re Napier*, 55 F.3d 610, 34 USPQ 2d 1782 (Fed. Cir. 1995). Absent such a showing, the Examiner has impermissibly used the Applicant's teaching to hunt through the prior art for the claimed

elements and combine them as claimed. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Notably, in each example directed to making devices (Examples 7-11), Pacetti et al. disclose dissolving their composition in non-biocompatible solvents (THF, xylene, chloroform and trichloroethane), spraying the solution onto a medical device, and baking the device at about 50°C to drive off the solvents.

One skilled in the art could not have derived motivation to spray such toxic components directly onto injured human tissues in order to form coatings. Withdrawal of the rejection is respectfully requested on this basis alone.

Further, Pacetti et al. provides no motivation to select Pemirolast from among the laundry list of possible drugs provided at column 9, lines 16-65, as suggested by the Examiner, especially in amounts effective to inhibit formation of post-operative adhesions.

In order to establish a *prima facie* case of obviousness, the skilled artisan would need to have a reason to select a particular component from such a laundry list:

It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. *In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965).

Pacetti et al. disclose Pemirolast as an antiallergic agent, and fail to disclose or suggest its use in inhibiting post-operative adhesions when applied locally to tissue. Since Pacetti et al. are entirely silent as to adhesion-prevention, one skilled in the art could not have been motivated to select Pemirolast from among the hundreds of disclosed drugs in the Pacetti et al. list cited by the Examiner,

especially in an amount effective to inhibit post-operative adhesions when applied locally to tissue.

Accordingly, Applicants respectfully submit that Pacetti et al. fails to establish a *prima facie* case of obviousness as to the present claims. Withdrawal of the rejection is respectfully requested.

Finally, Applicants note that the Examiner has failed to reject claim 31 in the outstanding Office Action. Applicants presume that such is an indication of the patentability of claim 31. Applicants request notification of the allowability of claim 31.

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478 (14758).

If the Examiner has any questions or wishes to discuss this application,

U.S. Serial No. 10/780,452

Response dated: April 15, 2010

Response to Office Action dated: September 16, 2009

the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

Date: April 15, 2010

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